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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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1M21/0922

EXAMINER

ART UNIT	PAPER NUMBER
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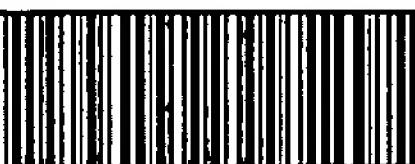
DATE MAILED: 09/22/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 08/900,414	Applicant(s) Knight et al.
Examiner N. Bhat	Group Art Unit 1761



Responsive to communication(s) filed on Oct 27, 1997

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

Claim(s) 1-12 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-12 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1761

DETAILED ACTION

1. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, applicant's Markush group is incorrectly stated. Applicant should recite "selected from the group consisting of 2-hydroxy-4-(methylthio)butanoic acid, salts, amines and esters thereof..." appropriate correction is required.
2. Claims 2-5 are rejected as being dependent upon a rejected base claim.
3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meade in combination with Nocek et al.[5,158,791]

Meade discloses the invention substantially as claimed.

Art Unit: 1761

Meade teach a water-insoluble, calcium or magnesium salt of and amino acid specifically, a salt of a methionine. Meade specifically teaches a method of providing a water insoluble calcium-dl-methionate which are stable and can be easily produced in large quantities for use as food additives for human consumption and as fed supplements for ruminant animals. Meade teaches that to achieve the optimum production of milk in ruminant animals the ruminants can be feed a proportion of their dietary requirements by using the water-insoluble amino acid salts which have the advantage that they will not undergo undesirable alteration or degradation of the rumen after ingestion and thus will not be available to the microorganisms of the rumen. Further, the amino acid salts do not interfere with the normal process of rumen fermentation. The amino acid salt bypass the normal fermentation and digestion processes of the ruminant animal and reach the abomasum or intestine of the ruminate in a form in which it can be absorbed permitting the ruminant to take the full advantage of the nutritive value of the amino acids. The addition of the water insoluble amino acid to feed supplements provides essential amino acids which enhance, meat production in beef cattle and milk production in lactating dairy cattle. [Note Column 1, lines 30-35, Column 2, lines 14-31, Column 7, lines 36-68, Column 8, lines 49-68 and Column 9, lines 15-38] Meade teach that the level of addition of the water insoluble amino acid salts for use in a feed supplement can vary over a wide range and can be selected based on known nutritional requirements. The levels of adding water insoluble calcium -L-lysine, calcium-dl-methionate or calcium L-ornithate is from about 20 grams per head of cattle a day to about 50 grams per head of

Art Unit: 1761

cattle per day. Meade teach that other levels of addition can be utilized and the precise level of addition will be selected according to well know nutritional criteria.

However, Meade does not teach using a model which determines the methionine needs of the ruminant based of the natural or synthetic feed ingredients and the nutrient composition of each of the ingredients.

Noek et al. teach a method of formulating dairy cow rations based on the amounts of ruminally available proteins (RAP) and carbohydrates (RAC) in the total daily rations, which includes both grain and forage components. Quantities necessary for determining RAP and RAC values are obtained form conventional chemical analysis and in situ techniques. Statistical analysis of experimentally obtained data showed optimized lactation response is obtained from a total daily ration containing RAP and RAC in the ranges of about 10.5-12.5% and 35%-45% respectively. Other factors such as microbial synthesis and feed escape proteins were also shown to be optimized by total dairy rations containing RAP and RAC levels within or near the lactation optimization ranges.

It would have been obvious from the combined teachings of Mead and Nocek et al. to provide a process for formulating ruminant food rations wherein the process comprise determining the methionine needs of the ruminant and supplementing the ruminant feed based on the forage component the grain component and adding an amino acid supplement which provides increased levels of amino acid in the ruminant which corresponding increases the milk production in lactating dairy cattle. Meade teaches a hydroxy analog of methionine which is water insoluble

Art Unit: 1761

which is readily absorbable by the ruminant animal which does not suffer the disadvantages of the prior art wherein the amino acid supplement was subject to degradation by microbes during digestion nor being subjected to an expensive coating process. Meade teaches that the water-insoluble hydroxy analog of methionine can be added as a feed supplement based on known nutritional criteria. Applicant has admitted in his specification that models for determining the methionine needs of the ruminant are well known, Nocek et al. teach such a method of formulating dairy cow rations based on rumen available protein and rumen available carbohydrate, to add the hydroxy analog of methionine such as taught by Meade in proportions based on the modeling taught in Nocek et al. substantially provides a process of formulating a ruminant food ration as claimed by applicant and to select and optimize the level of hydroxy analog of methionine to a 2-hydroxy-4-(methylthio)butanoic acid would have been obvious to one having ordinary skill in the art as it would have been expected that an increase in milk production would result in dairy cattle when methionine is provided in the diet of cattle such that the methionine supplement is added in amounts which are readily absorbed by the cattle and to optimize the amount of hydroxy methionine analog supplement would have been obvious absent criticality in showing. [Note the case law of *In re Aller*, 105 USPQ 223 and *In re Boesch*, 617 F.2d 272, 205 USPQ 215]

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hijiya et al. teach a ruminant feed additive which contains a phosphoric acid-amino acid-polyvalent metal composite salt which has excellent insolubility in a rumen of a ruminant and

Art Unit: 1761

excellent elution thereof in an abomasum and lower digestive organs. Rode et al. Teach a method for supplementing amino acid levels in ruminant animals which used coated methionine product. Sasaoka et al. Teach a ruminant feed which comprises one active substance such as amino acids, salts of amino acids and vitamins dispersed in a protectant containing calcium salts of mixed fatty acids. The feedstuff has excellent rumen bypassing properties and excellent digestion and absorption properties in the abomasum and subsequent digestive organs. Chung teach a nutritious composition containing raw soybean mild and raw cows' milk. Seaman et al. teach a method for preparing a high bypass protein product. Nocek et al. teach a method of formulating dairy cow rations based on carbohydrate regulation. Braund et al. teach a method of formulating diary cattle rations are formulated to optimize milk production.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina Bhat whose telephone number is (703) 308-3879. The examiner can normally be reached on Mondays through Friday from 9:20 AM to 6:00PM.

The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3602 . Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

NBhat
NINA BHAT
PRIMARY EXAMINER
GROUP 1300-1761